~~AF~~ 3738

PATENT
Customer No. 22,852
Attorney Docket No. 7528.0003-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Todd J. Mortier et al.	)	Group Art Unit: 3738
	)	
Application No.: 09/981,790	)	Examiner: D. Willse
	)	
Filed: October 19, 2001	)	
	)	
For: VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD	)	Confirmation No.: 6743
	)	

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL OF APPEAL BRIEF (37 C.F.R. 41.37)

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on October 17, 2005.

This application is on behalf of:

☒ Small Entity ☐ Large Entity

Pursuant to 37 C.F.R. 41.20(b)(2), the fee for filing the Appeal Brief is:

☒ $250.00 (Small Entity)

☐ $500.00 (Large Entity)

TOTAL FEE DUE:

Appeal Brief Fee	$250.00
Extension Fee (if any)	$65.00 (one month, small entity)

Total Fee Due $315.00

☒ Enclosed is a check for $315.00 to cover the above fees.

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this Appeal Brief, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge the fees necessary for such an extension to our Deposit Account No. 06-0916.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 23, 2006

By: _____
Leslie I. Bookoff
Reg. No. 38,084

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Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed October 17, 2005, further to Board Rule 41.37, and in response to the Notice of Panel Decision from Pre-Appeal Brief Review dated November 22, 2005, the period for response having been extended to January 23, 2006 (January 22, 2006, being a Sunday), by a Petition for Extension of Time pursuant to 37 C.F.R. § 1.136 - One Month - and fee payment filed concurrently herewith, Appellants submit one copy of this Appeal Brief and enclose herewith a check to cover the small entity appeal fee of $250.00 required under 37 C.F.R. § 41.20(b).

This Appeal Brief responds to the April 18, 2005, final rejection of claims 64, 66, 67, and 83.

If any additional fees are required or if the enclosed payment is insufficient, Appellants request that the required fees be charged to Deposit Account No. 06-0916.

Table of Contents

I. Real Party In Interest

The real party in interest is Myocor, Inc., the assignee of the entire right, title, and interest in the application.

II. Related Appeals and Interferences

Appellants, Appellants' legal representatives, and assignee are aware of no other appeals, interferences, or judicial proceedings that may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status Of Claims

Claims 1-91 were previously presented for examination. Of these claims, claims 1-58, 63, 65, and 69-82 were canceled, and claims 85-91 were not entered by the Examiner. Claims 59-62, 64, 66-68, 83, and 84 remain pending. Of these claims, claim 83 is the sole independent claim. Claims 64, 66, 67, and 83 are finally rejected. Claims 59-62, 68, and 84 are objected to as being dependent upon a rejected base claim, but allowable if rewritten in independent form to include all of the limitations of the base claims and any intervening claims. The final rejection of claims 64, 66, 67, and 83 is appealed.

IV. Status Of Amendments

No amendment has been filed subsequent to the final rejection.

V. Summary Of Claimed Subject Matter

An embodiment of the invention, as set forth in independent claim 83, for example, includes a method for treating an in situ mitral valve. See p. 2, ll. 15-16.[1] The method includes positioning a passive device 220, 320 with respect to a heart such that, throughout the cardiac cycle, a portion 225, 325 of the device 220, 320 contacts and passively alters a geometry of heart structure other than leaflets 16, chordae 18, papillary muscles 12, and an annulus associated with the in situ mitral valve 14. The passive device 220, 320 draws together leaflets 16 of the in situ mitral valve 14 to promote closure of the in situ valve 14. See, for example, Figures 9-10, the corresponding written description of those Figures, p. 6, ll. 18-25, p. 7, ll. 20-26, and p. 8, l. 13 - p. 9, l. 12.[2]

[1] The references to the specification and drawings in this Brief are merely intended to facilitate explaining how the originally-filed application provides exemplary embodiments and exemplary disclosure relating to the claimed subject matter. Those references should not be construed as limiting the claims.

[2] For a more detailed discussion of how the originally-filed application supports the pending claims, please see pages 4-6 of Appellants' response filed May 10, 2004.

VI. Grounds of Rejection to be Reviewed on Appeal

Claims 64, 66, 67, and 83 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,702,343 to Alferness ("Alferness").

VII. Argument

At pages 2-3 of the final Office Action dated April 18, 2005, claims 64, 66, 67, and 83 were rejected under 35 U.S.C. § 102(b) as being anticipated by Alferness. Appellants respectfully traverse this rejection because Alferness fails to teach each and ever element of independent claim 83.

A. The Relevant Law of Novelty

In order for a claim to be anticipated by a prior art reference under 35 U.S.C. § 102, each and every element in the claim must be found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1929 (Fed. Cir. 1989). *See* also M.P.E.P. § 2131.

B. Alferness Does Not Disclose the Recitations of Claim 83

Independent claim 83 is directed to a method of treating a mitral valve of a heart. Claim 83 recites

> positioning a passive device with respect to a heart such that, ***throughout the cardiac cycle***, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve, ***wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve***.

(Emphasis added.) The claimed device therefore includes a portion that contacts and alters heart geometry throughout the cardiac cycle, which includes diastolic filling and

systolic contraction. The device also draws together the heart valve leaflets to promote closure of the valve.

Alferness discloses a cardiac reinforcement device (CRD) and method for treating enlargement of the heart. More specifically, Alferness discloses applying a device to the epicardial (outer) surface of the heart to provide reinforcement of the cardiac wall during *only* diastole. *See, e.g.,* Alferness, col. 1, lines 8-14. Alferness explicitly teaches that the disclosed cardiac reinforcement devices do not provide cardiac assistance during systole, in contrast to prior art ventricular assistance devices. *See, e.g.,* Alferness, col. 3, lines 1-5, 11-14, and 33-38. Alferness further teaches that the cardiac reinforcement devices reduce cardiac dilation (enlargement) and thereby potentially reduce problems that are associated with such dilation. *See, e.g.,* Alferness, col. 1, lines 25-30, and col. 5, lines 26-44.

Therefore, there are two independent reasons why Alferness fails to teach each and every element of independent claim 83. Specifically, Alferness neither discloses nor suggests, either explicitly or otherwise, that "throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure" or that "the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve," as recited in independent claim 83. Each of these claim limitations and the reasons why Alferness fails to disclose or suggest them, either explicitly or otherwise, will be addressed individually.

a. Alferness does not disclose devices that act "throughout the cardiac cycle"

Alferness does not disclose altering the geometry of heart structure throughout the cardiac cycle, as recited in independent claim 83. To the contrary, as discussed above, Alferness explicitly teaches that the disclosed cardiac reinforcement devices act only during diastole and not during systole. Specifically, Alferness teaches that "[t]he present invention is directed to reinforcement of the heart wall during diastolic filling of a chamber of the heart." *See* Alferness, col. 2, lines 47-48. Indeed, Alferness goes on to teach that "[i]n contrast to known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole." *See* Alferness, col. 3, lines 1-5. Alferness explains that the CRD does not "impair[] systolic function." *See* Alferness, col. 3, lines 11-14.

Despite the explicit disclosure of the Alferness device acting only during diastole, the Examiner alleges that the teaching of Alferness to position a cardiac reinforcement jacket device under the parietal pericardium is a teaching of

> [altering] the geometry of the cardiac wall throughout the cardiac cycle by virtue of the device thickness shifting the cardiac wall inwardly from the parietal pericardium and the device material (and thickness) altering the dynamic response characteristics of the cardiac wall, the device, and the parietal pericardium in combination.

See April 18, 2005, Office Action at page 2.[3] Alferness, however, does not disclose that the device thickness shifts the heart wall inwardly throughout the cardiac cycle. In fact,

[3] The pericardium is a double-walled sac filled with serous fluid that encloses the heart and the roots of large blood vessels, such as the aorta. *See, e.g.,* Alferness, col. 2, lines 59-60.

Alferness does not discuss the device thickness anywhere in the disclosure, nor does the Examiner reference any such portion of Alferness.

Since Alferness contains no explicit disclosure that the disclosed cardiac reinforcement devices alter the geometry of heart structure throughout the cardiac cycle, it appears the Examiner may be relying on inherency principles to support the rejection based on Alferness. To establish inherency, the Examiner must show that "the missing descriptive matter is *necessarily* present" in the reference. *See* M.P.E.P § 2112, Original Eighth Ed., Aug. 2001, Revision May 2004 (*quoting in re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112 (emphasis in original.)

In the present case, the Examiner has not established that Alferness's disclosure of placing a cardiac reinforcement jacket under the parietal pericardium is necessarily a teaching of altering a geometry of heart structure throughout the cardiac cycle, as required by independent claim 83. This is especially true in light of Alferness's explicit disclosure that the disclosed devices act only during diastole and not during systole. To alter heart structure geometry throughout the cardiac cycle in the manner alleged by the Examiner, the disclosed cardiac reinforcement device at least would need a thickness sufficient to occupy the space between the heart and the pericardium. However, the possibility exists for a cardiac reinforcement device to have a thickness whereby the device does *not* occupy sufficient space between the pericardium and the cardiac wall so as to shift the cardiac wall inwardly or otherwise alter heart structure geometry throughout the cardiac cycle. In this regard, Alferness contains no disclosure in its text

regarding the thickness of the device. Since the Alferness patent does not contain any textual disclosure regarding the thickness of the disclosed devices, the figures of that patent provide the only indication of the size of the disclosed devices. Figure 5 best indicates the device size, since the device is shown in perspective view relative to a heart. That Figure shows the device thickness to be, for example, much less than a width of a main descending coronary vessel, which typically has a width of about 3-4 mm. In addition, rather than indicating that the device has any appreciable thickness, Figure 5 shows that the device disclosed by Alferness lies essentially flush with heart surface. Thus, it is likely that the devices disclosed by Alferness are intended to be positioned within the space between the pericardium and the heart, in a manner that does not shift the cardiac wall inward from the pericardium or otherwise alter heart structure geometry throughout the cardiac cycle. Therefore, since a device without sufficient thickness to occupy the space between the pericardium and the heart may exist, the Examiner has failed to establish inherency.

Additionally, in the Requests for Reconsideration filed on January 5, 2005, and September 19, 2005, Appellants requested that the Examiner supply evidence to support the assertion that the cardiac reinforcement devices disclosed by Alferness *necessarily* have the thickness required to perform the alleged functions. The Examiner did not supply such evidence. To the extent the Examiner may be relying on his own personal knowledge regarding the alleged thickness of the Alferness devices, 37 C.F.R. § 1.104(d)(2) requires the Examiner to supply an affidavit.

> When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the

> affidavit of such employee and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicants and other persons.

37 C.F.R. § 1.104(d)(2). The Examiner has not supplied such an affidavit or other evidence to support his conclusory assertions.

In the April 18, 2005, final Office Action, in response to the Appellants' arguments, the Examiner only provided the conclusory allegation that "the configuration or arrangement of the cardiac wall and the parietal pericardium is clearly altered (throughout the cardiac cycle) by the placement of an Alferness cardiac reinforcement device between these two natural structures." *See* April 18, 2005, Office Action at page 3. As explained above, in order for the Examiner's allegations to be accurate, the Alferness device at least must *necessarily* have a thickness greater than the space between the pericardium and the heart. Alferness simply does not discuss the thickness of the disclosed device, and the Examiner has not provided any evidence that any of the embodiments of the Alferness device possesses a thickness larger than the space between the pericardium and the heart.

Additionally, it is likely that it would be undesirable for the cardiac reinforcement devices disclosed by Alferness to have a thickness large enough to occupy sufficient space between the heart and the pericardium. Such a device could cause excessive compression of the heart in a uniform manner throughout the cardiac cycle. Such uniform, excessive compression could result in tamponade of the heart muscle, which is an undesirable compression of the heart typically caused by blood or fluid accumulation in the space between the heart and the pericardium.

Moreover, if the Examiner contends that any alleged altering of the pericardium by the Alferness device meets the claim limitation to "alter geometry of heart structure," Appellants note that the pericardium is not "heart structure." As Alferness recognizes, "[t]he heart is enclosed within a double walled sac known as the pericardium." Col. 2, lines 59-60. Thus, one skilled in the art recognizes that pericardium is something other than the heart.

For at least the above reasons, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an in situ mitral valve, as recited in claim 83, and the Section 102 rejection based on Alferness should be withdrawn.

b. Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve"

As a second independent basis to distinguish claim 83 from Alferness, Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve." In the Office Action of April 18, 2005, the Examiner asserts that column 1, lines 25-30, and column 5, lines 26-44 of Alferness allegedly teach that the cardiac reinforcement device of Alferness draws together leaflets of the in situ valve to promote closure of said valve. *See* Office Action at page 2. However, the cited passages, as well as the remainder of the disclosure in Alferness, describe a device that constrains cardiac expansion solely during diastole so as to prevent enlargement (*i.e.,* dilation) of the heart. These passages do not disclose or otherwise suggest a device that acts on the valve or draws together leaflets to close the valve. At most, Alferness may be interpreted to teach that use of the disclosed cardiac reinforcement devices for constraining cardiac expansion during diastole and preventing

cardiac dilation may reduce the naturally occurring consequences of valvular leakage. This, however, is not a teaching of a device that explicitly or inherently "draws together leaflets of the in situ valve to promote closure of the in situ valve."

In response to the Appellants' remarks in the Request for Reconsideration filed on January 5, 2005, the Examiner alleges that Alferness teaches a device that draws together valve leaflets to promote closure of the valve by disclosing that "[r]educed cardiac dilation can cause reduction in the problems associated with cardiac dilation such as arrhythmias and valvular leakage" and by disclosing embodiments where "the predetermined size can be adjusted for size reduction as the cardiac size is reduced." The Examiner also placed the burden on "[t]he Applicant [to] explain how the Alferness device reduces valvular leakage, if not by drawing together leaflets of the in situ valve." *See* Office Action of April 18, 2005, at page 3.

Appellants explained further, as set forth below, that the devices disclosed by Alferness do not draw together the leaflets of the mitral valve. *See* Appellants' September 19, 2005, Request for Reconsideration at pages 8-10. Alferness merely discloses a device that constrains cardiac expansion, which can provide reduced cardiac dilation. The reduction in ventricle size over time may help to facilitate the heart's natural ability to assuage some of the problems associated with cardiac dilation, such as arrhythmias and valvular leakage. In other words, any reduction in valvular leakage in a heart equipped with a device disclosed by Alferness stems from a fortuitous, natural response of the heart to being constrained against excessive cardiac expansion, not from the Alferness device acting in a way to draw the leaflets together.

Furthermore, as discussed above, Alferness explicitly teaches that the disclosed devices solely limit the outward expansion of the heart wall during diastolic chamber filling. *See, e.g.,* col. 2, lines 63-65. Indeed, Alferness explicitly states that "[t]he present invention is directed to reinforcement of the heart wall during diastolic filling of a chamber of the heart." *See, e.g.,* col. 2, lines 47-49. Additionally, as also noted above, Alferness explicitly states that unlike "known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole." *See, e.g.,* col. 3, lines 1-4.

"Diastolic filling" and "diastole" refer to the filling of the left ventricle with blood from the left atrium. During this time, the mitral valve is in an open configuration, so as to allow blood to exit the left atrium and enter the left ventricle. In contrast, "systole" refers to the contraction of the left ventricular muscle wall to expel blood from the left ventricle, through the aortic valve, and into the body. During systole, the mitral valve is in a closed configuration, so as to prevent backflow of blood into the left atrium.

Thus, since Alferness discloses devices that provide cardiac reinforcement only during diastole, a time when the mitral valve is naturally open, it is counterintuitive for the Alferness devices to "draw together leaflets of [an] in situ valve to promote closure of the in situ valve" during diastolic filling, as alleged by the Examiner. *Assuming arguendo* that the Alferness devices function as alleged by the Examiner, the devices would urge the mitral valve to close only when the valve is naturally designed to be open, which may hinder the natural functions of the heart.

For at least the above reasons, therefore, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an in situ mitral valve, as

recited in claim 83. Accordingly, Appellants respectfully request that the Section 102 rejection based on Alferness be withdrawn and claim 83 and its dependents allowed.

VIII. Conclusion

For the reasons explained above, pending claims 59-62, 64, 66-68, and 83-84 are allowable, and reversal of the Examiner's rejection of claims 64, 66, 67, and 83 over Alferness is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 23, 2006

By: _____
Leslie I. Bookoff
Reg. No. 38,084

IX. Appealed Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

59. The method of claim 83, wherein positioning the device includes extending at least a portion of at least one elongate member within a chamber of the heart and anchoring an end of the at least one elongate member to one of a wall surrounding the heart chamber and a papillary muscle in the chamber.

60. The method of claim 59, wherein positioning the device further includes anchoring another end of the elongate member proximate the annulus of the valve.

61. The method of claim 59, wherein the at least one elongate member includes a tension member.

62. The method of claim 59, wherein the at least one elongate member includes a plurality of elongate members.

64. The method of claim 83, wherein the heart structure includes a wall of a heart chamber.

66. The method of claim 83, wherein altering the geometry of the heart structure includes altering at least one of a transverse radial dimension and vertical dimension of a heart chamber during at least a portion of the cardiac cycle.

67. The method of claim 66, wherein altering at least one of the transverse radial dimension and vertical dimension includes reducing at least one of the transverse radial dimension and vertical dimension.

68. The method of claim 83, wherein positioning the device includes positioning the device so as to alter a position of at least one papillary muscle associated with the valve.

83. A method of treating an in situ mitral valve, the method comprising:

positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve, wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve.

84. The method of claim 68, wherein altering the position of the at least one papillary muscle associated with the valve includes drawing the at least one papillary muscle toward the valve.

X. Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

None.

XI. Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

None.